UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

8/20/2018

SUBJECT: Acute Toxicity Review for *XHC-E*, EPA Reg. No.: **1677-254**, DP 447104

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TO : Demson Fuller, PM/ Team 32 /Wanda Henson
Regulatory Management Branch II
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Registrant: Ecolab, Inc			
Action Code A570	Decision No.: 540734	Submission No.: 1019265	E-Sub No.: 28911
MRID No(s).: 46441106-12, 43940801-02, and 44175501			

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
014703	7681-52-9	Sodium Hypochlorite	0.58
		Other Ingredients	99.42
		Total	100.00

I. BACKGROUND

The Registrant, Ecolab, Inc, has submitted ten acute toxicity studies to support a reduction of a signal word on the label of their product: *XHC-E*, EPA Reg. No. 1677-254. The subject product is a one-step disinfectant cleaner on hard, non-porous surfaces.

The data package included:

1. Cover letter from Registrant to EPA, dated 5/1/2018.
2. Application for pesticide registration, Form 8570-1.
3. Basic CSF, dated 5/1/2017.
4. Data matrix, dated 5/1/2018.
5. Proposed label, dated 5/1/2018.
6. Transmittal document, dated 5/1/2018.

II. FINDINGS/RECOMMENDATIONS

1.1. Studies provided were conducted with EPA Reg. Nos. 56392-7 (0.65% A.I.) and 56392-10 (0.62% A.I.) which are substantially similar to the subject product.

1.2. All acute toxicity studies cited and reviewed show no toxicity with the subject product. However, this result is not in compliance with high pH of this product. In particular, the result is questionable regarding the Primary Eye Irritation endpoint.

1.3. The acute toxicity profile of *XHC-E*, EPA Reg. No. 1677-254, is currently:

GRN	Study	MRID	Toxicity Category	Status
870.1100	Acute Oral Toxicity	46441106	IV[1]	Cited
		46441107	IV[1]	Cited
870.1200	Acute Dermal Toxicity	46441108	IV[1]	Cited
		44175501	IV	Accepted
870.1300	Acute Inhalation Toxicity	46441109	IV[1]	Cited
		43940801	IV[2]	Cited
870.2400	Primary Eye Irritation	46441110	IV[1]	Cited
870.2500	Primary Skin Irritation	46441111	IV[1]	Cited
870.2600	Dermal Sensitization	46441112	Non- sensitizer[1]	Cited
		43940802	Non- sensitizer[2]	Cited

[1] Based on the RSB's review for EPA Reg. No. 56392-RN (10) (DP312656, 3/17/2005)

[2] Based on the RSB's review for EPA Reg. No. 56392-7 (DP225846, 5/17/1996)

CONCLUSION

The acute toxicity requirements have been satisfied to support the label amendment of the subject product, EPA Reg. No. 1677-254.

III. PRODUCT LABELING

Based on the above acute toxicity profile (Category IV) for ***XHC-E*, EPA Reg. No. 1677-254,** no specific First Aid or human-hazard precautionary statements (or headings) are required.

1) The registrant may choose to include front-panel statement "Keep Out of Reach of Children" (KOROC). The Agency PM may, in accordance with 40 CFR §156.66, decide whether to waive the KOROC requirement, and whether to approve its placement on other than the front panel (https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf).

2) The presence of the signal word is optional. If one is used, it must be "CAUTION".

3) The registrant may also choose to use category III for labeling (Precautionary & First Aid statements), as the acute toxicity profile indicates that the subject product is Toxicity Category IV (https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf).

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

Product Manager: Demson Fuller / 32 **Reviewer:** B.S. Yurchak
MRID No.: 44175501 **Study Completion Date:** 10/01/1996
Study No.: GR1399

Testing Laboratory: Gibraltar Laboratories, Inc
Author: Jevon Krushenick

Quality Assurance (40 CFR §160): Included

Test Material: *XC 20003.05,* a liquid (substantially similar to EPA Reg. No. 56392-7)
Dose levels: 5000 mg/kg bw

Animals: New Zealand albino rabbits
Number/Sex: 5/sex
Age: Adults (age in weeks not specified)
Weight: 1.89 – 2.11 kg (male/female)
Source: Hare Marland, Inc

Method: OECD 402 (1987); USEPA Guideline 81-2

Summary:

1. **Estimated LD_{50}:** > 5000 mg/kg bw for each sex
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

Deviations from Guideline 870.1200:

1. The study was completed in 1996, prior to the release of the harmonized test guideline OPPTS 870.1200 in August 1998, but the study does adequately meet the intent of the guideline.
2. The percentage of the body surface area covered by the test substance is not provided.

Procedure:

The test material was applied topically to the bare skin to cover the area of the sacrospinalis and external oblique muscles under two-ply gauze dressing of an appropriate size to maintain the test material in place. The dose rate was 4.95 mL or the test material per kilogram of body weight (specific gravity 1.01). The test site was covered with plastic wrap and a cotton stockinette secured on both ends with masking tape.

Results:

After 24 hours the occlusive patch was removed and the animals were observed daily for signs of toxicity for 14 days. Ten of ten rabbits survived 14 days following administration of 5 g/kg of

the test material. All animals appeared healthy throughout the test period and gained weight. No gross abnormalities expected to result from test material administration were observed at terminal necropsy.

Table 1. Mortality			
Dose (mg/kg bw)	Number Dead / Number Tested		
	Males	Females	Combined
5000	0 / 5	0 / 5	0 / 10